AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Southern District of Indiana on the following ☑ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
1:08-cv-01302-DFH-TAI	9/26/2008	Southern District of Indiana

PLAINTIFF	DEFENDANT
ELI LILLY AND COMPANY	TEVA PARENTERAL MEDICINES, INC. and TEVA PHARMACEUTICALS USA, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	4,808,614	2/28/1989	ELI LILLY AND COMPANY
2	5,464,826	11/7/1995	ELI LILLY AND COMPANY
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☒ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
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4		
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Jeffrey A. Griggs	Laura B. Kirby	9/29/2008

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY

Plaintiff,

v.

TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC.

Defendants.

Civil Action No.: 1:08-cv-1302-DFH-TAB

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Teva Parenteral Medicines, Inc. (formerly known as SICOR Pharmaceuticals, Inc.) ("Teva Parenteral") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Defendants"). This action involves two patents. The first patent concerns the pharmaceutical product, GEMZAR®. The second patent concerns the use of this pharmaceutical product as a treatment for susceptible neoplasms.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Upon information and belief, Defendant Teva Parenteral is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, Teva Parenteral is a wholly owned and directly controlled subsidiary of Teva USA.

Upon information and belief, Teva Parenteral develops and markets generic injectable drug products, which constitute Teva USA's line of injectable products.

3. Upon information and belief, Teva USA is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA markets a wide range of generic products, and specifically markets injectable drug products through and with Teva Parenteral. Upon information and belief, Teva USA expanded its business into the area of generic injectable drug products through its acquisition of SICOR Pharmaceuticals, Inc., now known as Teva Parenteral.

4. Upon information and belief, Teva USA acquired Teva Parenteral in January 2004, and since then has endeavored to completely integrate Teva Parenteral's business into the operations of Teva USA.

5. Upon information and belief, Teva USA markets generic drug products in the Southern District of Indiana and throughout the United States through and with its wholly owned and directly controlled subsidiary Teva Parenteral.

6. Upon information and belief, Teva USA uses and works with Teva Parenteral to carry out its business of importing, manufacturing, formulating, filling, labeling, and packaging finished dosage forms of injectable generic drug products for distribution in the Southern District of Indiana and throughout the United States.

7. The Court has personal jurisdiction over the Defendants because they have maintained continuous and systematic contacts with Indiana; and have purposefully availed themselves of the benefits and protections of the laws of Indiana.

8. This patent infringement action arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2). Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

9. United States Patent No. 4,808,614 ("the '614 patent"), entitled "Difluoro Antivirals and Intermediate Therefor," was duly and legally issued to Lilly by the United States Patent and Trademark Office on February 28, 1989. The '614 patent expires on May 15, 2010, followed by a six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(a), ending on November 15, 2010. A true and correct copy of the '614 patent is attached as Exhibit A. Lilly has owned the '614 patent since it issued.

10. United States Patent No. 5,464,826 ("the '826 patent"), entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides," was duly and legally issued to Lilly by the United States Patent and Trademark Office on November 7, 1995. The '826 patent expires on November 7, 2012, followed by a six-month period of market exclusivity granted by the FDA under 21 U.S.C. § 355(a), ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit B. Lilly has owned the '826 patent since it issued.

11. Lilly is the holder of approved New Drug Application No. 20-509 for the use of Gemzar as a treatment for non-small cell lung cancer, pancreatic cancer, breast cancer, and ovarian cancer.

12. Upon information and belief, Teva Parenteral filed or caused to be filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 90-644

under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of gemcitabine hydrochloride (2g base/vial). Upon information and belief, Teva Parenteral filed or caused to be filed ANDA No. 90-644 to obtain approval to market its generic product before the expiration dates of the '614 or '826 patents. Upon information and belief, ANDA No. 90-644 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the '614 and '826 patents are invalid or would not be infringed.

13. Upon information and belief, Teva USA participated in the submission of ANDA No. 90-644 or otherwise acted in concert with Teva Parenteral in the submission of ANDA No. 90-644.

14. Upon information and belief, Teva USA exercises control over Teva Parenteral and conducts its U.S. injectable generic drug product operations through and with Teva Parenteral.

15. Upon information and belief, if ANDA No. 90-644 is approved, it is the intention of Teva USA and Teva Parenteral that the product will be distributed in the United States by or through Teva USA and/or Teva Parenteral.

16. Teva Parenteral caused to be sent to Lilly a letter ("Notice Letter") dated August 29, 2008, notifying Lilly that Teva Parenteral filed ANDA No. 90-644 for Gemcitabine Hydrochloride for Injection (2g base/vial) and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received the Notice Letter via Federal Express Delivery on or about September 2, 2008. The Notice Letter alleges noninfringement of claims 3-6, 9-10, and 13-14 of the '614 patent and claims 3-5 of the '826 patent. The Notice Letter further alleges that claims

1-2, 7-8, and 11-12 of the '614 patent are invalid for one reason, and that claims 1-2 and 6-7 of the '826 patent are invalid for two reasons.

17. Under 35 U.S.C. § 271(e)(2)(A), Teva Parenteral's submission to the FDA seeking approval for the commercial manufacture, use, or sale of Gemcitabine Hydrochloride for Injection before the expiration of the '614 and '826 patents constitutes an act of infringement. If ANDA No. 90-644 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride for Injection would infringe at least claims 8 and 12 of the '614 patent and claims 2 and 7 of the '826 patent under 35 U.S.C. § 271(a)-(c).

18. Upon information and belief, Teva Parenteral has filed ANDA No. 90-644, seeking authorization to commercially manufacture, use, offer for sale, and sell the Gemcitabine Hydrochloride for Injection pharmaceutical product. On information and belief, Defendants know that physicians will use Gemcitabine Hydrochloride for Injection in accordance with the indications sought by Teva Parenteral, and will therefore infringe one or more claims of the '614 patent and the '826 patent.

19. Upon information and belief, Defendants had actual knowledge of the '614 and '826 patents prior to filing ANDA No. 90-644 and did not exercise due care in analyzing the '614 and '826 patents and presenting arguments in the paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and in the Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

20. Lilly will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

21. Lilly realleges and incorporates by reference paragraphs 1-20.

22. This declaratory judgment counterclaim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

23. Upon information and belief, Teva Parenteral has filed an ANDA with the FDA seeking authorization to commercially manufacture, use, offer for sale, and sell its Gemcitabine Hydrochloride for Injection pharmaceutical product.

24. Upon information and belief, Teva Parenteral seeks approval of at least one indication claimed in the '826 patent for the Gemcitabine for Injection pharmaceutical products.

25. Upon information and belief, Defendants know that physicians will use Gemcitabine Hydrochloride for Injection in accordance with the indications sought by Teva Parenteral and will therefore infringe one or more claims of the '614 and '826 patents, either literally or under the doctrine of equivalents.

26. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell Gemcitabine Hydrochloride for Injection soon after the FDA approves such indications.

27. Such conduct will constitute direct infringement of one or more claims of the '614 patent under 35 U.S.C. § 271(a), inducement of infringement of the '614 and '826 patents under 35 U.S.C. § 271(b), and contributory infringement of the '826 patent under 35 U.S.C. § 271(c).

28. Defendants' infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 90-644.

29. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Defendants concerning liability for the infringement of the '614 and '826 patents. Defendants' actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Defendants as follows:

(a) declaring United States Patent Nos. 4,808,614 and 5,464,826 not invalid and not unenforceable;

(b) declaring that Defendants would infringe one or more claims of United States Patent No. 4,808,614 by the threatened acts of commercial manufacture, use, offer to sell, and sale of its Gemcitabine Hydrochloride for Injection pharmaceutical product prior to the expiration of said patent;

(c) declaring that Defendants would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of commercial manufacture, use, offer to sell, and sale of its Gemcitabine Hydrochloride for Injection pharmaceutical product prior to the expiration of said patent;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Teva Parenteral's ANDA No. 90-644 relating to Gemcitabine Hydrochloride for Injection before the expiration of the six-month periods of market exclusivity for the '614 and '826 patents granted under 21 U.S.C. § 355(a), which follow the expiration of the patents;

(e) enjoining Defendants from the commercial manufacture, use, offer to sell, sale, or importation of their Gemcitabine Hydrochloride for Injection product, in accordance with 35 U.S.C. § 271(e)(4)(B);

(f) declaring this to be an exceptional case and awarding Lilly attorney's fees under 35 U.S.C. §§ 285 and 271(e)(4); and

(g) awarding Lilly any further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: September 26, 2008 By: Jan M. Carroll

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